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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document are accurate and complete to the best of KSEA's knowledge.

Applicant:

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Contact:

Marika Anderson
Regulatory Affairs Specialist

Device Identification:

Common Name

Endoscope
Telescope sheaths
Knives
Scissors
Dissectors
Bipolar Forceps and Cable
Adapter

Trade Name

KSEA Instrument Set for Endoscopic Surgery of Superficial Veins and Fascia of the Lower Extremities

Indication: The KSEA Instrument Set for Endoscopic Surgery of Superficial Veins and Fascia of the Lower Extremities is intended for use by qualified surgeons during endoscopic surgery of superficial veins and fascia of the lower extremities, including vein dissection and paratibial fasciotomy.

Device Description: The KSEA Instrument Set for Endoscopic Surgery of Superficial Veins and Fascia of the Lower Extremities are manually operated, reusable surgical devices consisting of a rigid endoscope, sheath, scissors, forceps, knives, and adapters. The instruments and endoscope are long enough to gain access to the surgical site. The body contact materials have a long history of use in medical devices and do not pose any new issues of safety and effectiveness.

Substantial Equivalence: The KSEA Instrument Set for Endoscopic Surgery of Superficial Veins and Fascia of the Lower Extremities is substantially equivalent to the predicate devices since the basic features, design and intended uses are the same. The minor differences in design and dimensions between the KSEA Instrument Set for Endoscopic Surgery of Superficial Veins and Fascia of the Lower Extremities and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no effect on the performance, function or intended use of these devices.

Signed:

Marika Anderson

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Regulatory Affairs Specialist